DETAILED ACTION

1. This office action is in response to application no. 10/579174 filed on 11/12/2008.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: Applicant has failed to comply with the provision of MPEP 201.11 (III), which requires that the relationship be indicated between the prior filed non-provisional application(s) and the instant application. See 37 CFR 1.78(a)(2)(i). The relationship between the applications is whether the instant application is a continuation, divisional, or continuation-in-part of the prior nonprovisional application.

Information Disclosure Statement

3. The information disclosure statements (IDS) submitted on 02/12/2009 and 02/02/2010 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the solenoid or coils

must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim(s) 1, 4, 11, 12 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. In claim 1, the method step labeled "e." appears redundant, considering that the electric field amplitude is known (see step "a.").

8. Claim 1 recites the limitation "the voltage and current" in step "a." of the claim. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 4 recites the limitation "the diseased human hip" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

10. In claims 11, 12 and 18, it is unclear how an electric field of 20 mV/cm is achieved with a current density of 120 $\mu A/cm^2$ given that this relationship requires a conductance of the synovium and articular cartilage of 0.6 mS/m. This calculated conductance is in direct opposition with applicants disclosed conductance of cartilage at TABLE 1B on page 9 which is listed as 0.6 S/m.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claim(s) 1, 11, 12, 18 and all dependents are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim(s) 1, 16, 17 and 23 of U.S. Patent No. 7,022,506. Although the conflicting claims are not identical, they are not patentably distinct from each other because all of the claims are directed at a specific treatment for osteoporosis. The narrowing of the range of voltages and currents from those claimed in the patent to those of the instant application would not require undue experimentation and would have been obvious to one of ordinary skill

in the art at the time of the invention. Furthermore, reference is made in the patent to hips being affected by osteoporosis (Col. 2; ll. 1 – 19), suggesting that the claimed method in the instant application would be effective in treating hips as well as knees.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claim(s) 1, 2, 4, 10 - 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Brighton et al. (US 4,467,808, herein Brighton)** in view of **Zhuang et al. "Electrical Stimulation Induces the Level of TGF-β1 mRNA in Osteoblastic Cells by a Mechanism Involving Calcium/Calmodulin Pathway." (herein Zhuang)** (both cited in an IDS).

The instant claims are drawn to a device which comprises, in certain embodiments, electrodes adapted for a patient's knee joint or hip joint, driven by a signal generator which produces, across the electrodes, 20 mV/cm ± 15% (and, optionally, 120 $\mu A/cm^2$ ± 15%), more narrowly recited as being at 60 kHz in claims 14-17.

Brighton teaches, (Fig. 1), a device comprising electrodes to be attached to the knee joint of a patient, which electrodes are energized by a generator which produces AC current at 20 – 100 KHz. At column 4, line 15, it is taught that the device can produce 60 KHz. In the Abstract, it is taught that a range of about 5 to 15 volts may be produced from the device. In Col. 3, ll. 11 – 23, it is taught that the device of Brighton may be applied to multiple regions of the body affected by osteoporosis, including hips.

Zhuang teaches that stimulation resulting in an electric field of amplitude 20 mV/cm at 60 KHz promotes the activity of transforming growth factor β1 (TGF-β1) an important component in bone cell growth, maintenance and repair (pg. 225 under Materials and Methods; pg. 226 under Results and Discussion). Electric field and

current density are immutably linked via conductivity, a measurable quantity, generally represented as σ.

17. Given the teachings of Zhuang, one of ordinary skill in the art at the time of the invention would have found it obvious to update the device and method of Brighton to optimize the stimulation parameters to provide an electric field amplitude of 20 mV/cm, since Zhuang shows that this amplitude would provide increased healing of the treated tissue.

18. Further, regarding **claim 1,** it would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the electrode surface area, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).* (In the instant case, the result effective variable is surface area of the electrode, as the surface area of the electrode is linked to the current density. The optimum value (20 mV/cm) of the electric field is known as is the conductivity of the tissue being treated.)

The further limitations of claim 1 are considered inherent to Brighton.

Regarding **claim(s) 2, 4 and 10**, Brighton in view of Zhuang discloses the use of two electrodes (Brighton: Fig. 1) and that the therapy may be applied to the diseased human hip (Brighton: Col. 3, ll. 11 – 22).

19. Further regarding **claim(s) 11, 12 and 18,** it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide stimulation that results in an electric field strength of 20 mV/cm ± 15%, since it has

been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

In re Aller, 105 USPQ 233.

With regard to **claim(s) 13 and 19,** the examiner is taking **Official Notice** of the immutable relationship between voltage and current known as Ohm's Law (V=I*R) and the relationship of resistance to resisitivity, in which resistance is equal to resisitivity multiplied by length and divided by cross sectional area of the material in question.

20. Given that resistance of materials changes with the material dimensions (length and cross sectional area), it would have been obvious to one of ordinary skill in the art at the time of the invention to alter the output of a signal generator based on the size of the tissue to be treated.

Regarding **claim(s) 14 – 17 and 20 – 23,** Brighton in view of Zhuang discloses a range of about 5 to 15 volts may be produced from the device and that the device can produce 60 KHz. (Brighton: Abstract; Col. 4, l. 15).

21. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Brighton et al. (US 4,467,808, herein Brighton)** in view of **Zhuang et al. "Electrical Stimulation Induces the Level of TGF-β1 mRNA in Osteoblastic Cells by a Mechanism Involving Calcium/Calmodulin Pathway." (herein Zhuang)** in view of **Pollack et al. (US 5,014,699, herein Pollack)** (all cited in an IDS)..

With regard to **claim 3,** Brighton in view of Zhuang fail to disclose applying the voltage and current to the human using a solenoid or coil in the case of inductive coupling.

Pollack teaches applying the voltage and current to the human using a solenoid or coil in the case of inductive coupling (Fig. 4).

22. All of the component parts are known in the art as illustrated by Brighton, Zhuang and Pollack. The simple combination of prior art elements of a method of treating diseased tissue with the associated improvement of a solenoid to yield the predictable result of non-invasive therapy delivery would have been obvious to one of ordinary skill in the art at the time of the invention. *KSR*, 550 U.S. 82 USPQ2d.

Allowable Subject Matter

23. Claim(s) 5 – 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUTHER BEHRINGER whose telephone number is (571)270-3868. The examiner can normally be reached on Mon - Thurs 9:00 - 6:30; 2nd Friday 9:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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